REMARKS

In the Office Action mailed on February 2, 2005, the Examiner rejected all pending claims 1-20. By this response, Applicants have amended claims 1-20, and Applicants respectfully request reconsideration of amended claims 1-20 in view of the remarks set forth below.

Objections to Claims

The Examiner objected to claims 1 and 5 because of certain informalities. Accordingly, claims 1 and 5 have been amended to correct such informalities. Furthermore, claims 1 and 5, as well as the remaining claims, have been amended to make them easier to read. Applicants respectfully submit that none of the amendments narrow the scope of claims 1-20.

Rejections Under 35 U.S.C. § 102

The Examiner rejected claims 1-4 under 35 U.S.C. § 102(b) as being anticipated by Sakai et al. reference (U.S. Pat. No. 4,942,877)("Sakai"). Specifically, the Examiner stated:

> Saiki teaches a pulse oximeter sensor 1 and a memory 56. (Fig. 1 of Sakai). It is noted that the limitation "said memory containing data relating to said sensor and containing a digital signature" was not given any patentable weight since this limitation related only to a data structure contained in the memory. In other words, the memory only contains 0's and 1's and nothing in the claimed invention provides meaning to those 0's and 1's. Therefore, the data stored in the memory of the claimed invention is not distinguishable from the data stored in the memory of Sakai since both sets of data are merely 0's and 1's in a structural sense. In regard to claims 2-4, the limitations in those claims are attempting to narrow the scope of the data stored in the memory of the claimed invention but, as stated above, the particular data stored in the memory of the claimed invention is not distinguishable from the data stored in the memory of Sakai since the data in the memory of

> Sakai and the data in the claimed invention are both merely 0's and 1's in a structural sense.

Office Action, pages 2-3.

Applicants respectfully traverse this rejection. Anticipation under 35 U.S.C. § 102 can be found only if a single reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 U.S.P.Q. 773 (Fed. Cir. 1985). For a prior art reference to anticipate under 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). To maintain a proper rejection under 35 U.S.C. § 102, a single reference must teach each and every limitation of the rejected claim. *Atlas Powder v. E.I. du Pont*, 750 F.2d 1569 (Fed. Cir. 1984). Accordingly, the Applicants need only point to a single element not found in the cited reference to demonstrate that the cited reference fails to anticipate the claimed subject matter.

Further, when a computer program is recited in conjunction with a physical structure, such as a computer memory, Office personnel should treat the claim as a product claim. M.P.E.P. § 2106(IV)(B)(1)(a). Indeed, such data stored on a general purpose device renders the general purpose device a "new machine." *Cf. In re Alappat*, 31 U.S.P.Q.2d 1545, 1555-58 ("[A] general purpose computer becomes a special purpose computer once it is programmed."). Furthermore, the U.S.P.T.O. has specifically recognized that a computer readable medium having data encoded thereon is patentable subject matter. A claimed and encoded computer readable medium is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. M.P.E.P. § 2106(IV)(B)(1)(a). All words in a

claim must be considered in judging the patentability of that claim against the prior art. *In re* Wilson, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *see* M.P.E.P. § 2143.03.

Turning to the claims, independent claim 1 recites, *inter alia*, "[a]n oximeter sensor comprising ... a memory ... containing data relating to the sensor and containing a digital signature." Applicants respectfully assert that by storing data and a digital signature within a memory of a sensor, as recited in the present claims, the memory becomes a new machine. Accordingly, the mere disclosure of a *sensor having a memory* fails to anticipate the present claims. Specifically, Applicants assert that the Sakai reference's disclosure of a probe having a memory circuit is not sufficient to anticipate the present claims because all of the claimed features are not present. In contrast to the present claim recitations, the Sakai reference merely teaches a probe 1 having a red light emitting diode (RLED) 20, an infrared light emitting diode (IRLED) 21, a light receiving element 25, and a memory circuit 56 that stores "eleven items with respect to the *properties of the light or ray* of the RLED 20 and the IRLED 21." Sakai et al., col. 3, lines 13-58 (emphasis added). Applicants assert that the Sakai reference is deficient because none of these eleven stored items correspond to the claimed digital signature recited in the present claims. Indeed, the Examiner recognized the deficiency of the Sakai reference, yet ignored the claim language that distinguishes over the Sakai reference.

For the reasons set forth above, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102 of claims 1-4.

Rejections Under 35 U.S.C. § 103

The Examiner rejected claims 1, 16, 19 and 20 under 35 U.S.C. § 103(a) as being unpatentable over the Kiani et al. (U.S. Pat. No. 5,995,855)("Kiani") in view of Kinast U.S. Pat. No. 5,987,343) ("Kinast"). Specifically, the Examiner stated:

> In regard to claims 1 and 16, Kiani teaches an oximeter sensor 402 and an adapter with information element reader 1420. (Fig. 14 of Kiani). Kiani further teaches that the array 1420 is a predetermined set of different information elements that correspond to the possible sensors that the monitor 404 accepts. (column 14, lines 20- 22 of Kiani). Kinast teaches an EEPROM memory is one such information element. (Abstract and Fig. 2 of Kinast). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the memory of Kinast in the adaptor of Kiani since Kinai teaches that a predetermined set of different information elements are used and Kinast teaches one such information element. It is noted that the limitation "said memory containing data relating to said sensor and containing a digital signature" was not given any patentable weight since this limitation related only to a data structure contained in the memory. In other words, the memory only contains 0's and 1's and nothing in the claimed invention provides meaning to those 0's and 1's. Therefore, the data stored in the memory of the claimed invention is not distinguishable from the data stored in the memory of Sakai since both sets of data are merely 0's and 1's in a structural sense.
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> In regard to claim 19, Kiani teaches an oximeter sensor 402 and an adapter with information element reader 1420. (Fig. 14 of Kiani). Kiani further teaches that the array 1420 is a predetermined set of different information elements that correspond to the possible sensors that the monitor 404 accepts. (column 14, lines 20-22 of Kiani). Kinast teaches an EEPROM memory is one such information element. (Abstract and Fig. 2 of Kinast). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the memory of Kinast in the adaptor of Kiani since Kinai teaches that a predetermined set of different information elements are used and Kinast teaches one such information element. It is noted that the limitation "said memory containing sensor data and containing a digital signature" was not given any patentable weight since this limitation related only to a data structure contained in the memory. In other words, the memory only contains 0's and 1's and nothing in the claimed invention provides meaning to those 0's and 1's. Therefore, the data stored in the memory of the claimed invention is not distinguishable from the data stored in the memory of Sakai since both sets of data are merely 0's and 1's in a structural sense. In regard to

claim 20, Kiani teaches an internal monitor and a conditioning circuit. (Fig. 10 of Kiani).

Office Action, pages 3-5.

Applicants respectfully traverse this rejection. The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (P.T.O. Bd. App. 1979). To establish a *prima facie* case of obviousness, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (Bd. Pat. App. & Inter. 1985). A statement that the proposed modification would have been "'well within the ordinary skill of the art'" based on individual knowledge of the claimed elements cannot be relied upon to establish a *prima facie* case of obviousness without some *objective reason to combine* the teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993); *In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d. 1313, 1318 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d. 1161 (Fed. Cir. 1999).

A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness. *See* M.P.E.P. § 2146(X)(1). Additionally, it is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983); M.P.E.P. § 2145. Moreover, if the proposed modification or combination of the prior art would change the principle of operation of the prior art

invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959); *see* M.P.E.P. § 2143.01.

In regard to the Examiner's rejection of claims 1, 16, 19 and 20, Applicants respectfully submit that the Examiner has inappropriately ignore claim recitation regarding the content the sensor memory. Indeed, neither the Kiani reference nor the Kinast reference discloses a memory on a sensor or on a sensor adaptor that contains digital signature as set forth in the present claims. Therefore, the present claims are patentable over the cited combination for the same reasons as set forth above with respect to the Sakai reference.

Further in regard to the Examiner's rejection of claims 1, 16, and 19, Applicants respectfully submit that the combination proposed by the Examiner is not supported by the teachings of the cited references. The Examiner correctly noted that the Kiani reference teaches an oximeter sensor 402 having an adaptor with an information element reader 1420 and the information element reader 1420 is designed to read the information element 452 of the sensor 402 and translate that information into a form that the monitor 404 can accept. The examiner is further correct in noting that the Kinast reference teaches that an EEPROM may be an "information element" of a sensor. However, Applicants respectfully submit that the Examiner is incorrect in stating it would have been obvious to one of ordinary skill in the art to use the "information element" EEPROM described in the Kinast reference in the adapter of the Kiani reference (presumably in place of the information element reader 1420). As taught by the cited references and as admitted by the Examiner, the EEPROM of the Kinast reference is a type of "information element" that may be found in a *sensor*.

Therefore, when faced with the teachings of the cited references, one of ordinary skill in the art would, at best, be include to replace the coated resistor "information element" 452 of the Kiani reference with an EEPROM "information element" of the Kinast reference – one of ordinary skill in the art would have *not* be inclined to place the EEPROM information element" of the Kinast reference in the sensor *adaptor* of the Kiani reference. Therefore the cited references provide no teaching whatsoever to place a memory of any kind in a sensor *adaptor* much less a memory containing the type of information as claimed. Therefore, Applicants respectfully submit that claims 1, 16 and 19 are patentable over the cited art for this reason as well.

Further in regard to the Examiner's specific rejection of claim 20, Applicants respectfully disagree that the Kiani reference teaches an adaptor having an internal monitor in Fig. 10 as asserted by the Examiner. Fig. 10 discloses a particular example of an active gain stage 434 (Fig. 4). Therefore, at best, the Kiani references teaches an adaptor having circuitry that alters the gain of the signal passing through the adaptor – it does not teach that the adaptor include an internal monitor of any kind. Therefore, Applicants respectfully submit that claim 20 is allowable over the prior art for this reason as well.

In view of the remarks set forth above, Applicants respectfully submit that the subject matter of claims 1, 16, 19, and 20 is patentable over the cited combination. Therefore, Applicants respectfully request withdrawal of the Examiner's rejection and allowance of claims 1, 16, 19 and 20.

The Examiner rejected claims 1-6, 8-12, 14, and 15 under 35 U.S.C. § 103(a) as being unpatentable over the Osadchy et al. reference ("Osadchy") in view of Rosenheimer et al. reference ("Rosenheimer"), and further in view of the Kinast reference . Specification, the Examiner stated:

> Osadchy teaches a microcircuit in a catheter connector, which has a calibration code. The code is encrypted using an RSA encryption scheme using a public key and a private key. (page 6, lines 18-31 of Osadchy). The catheter provides the physiological signal and the microcircuit has that calibration code which is data relating to the catheter and contains a digital signature in the form of the RSA encryption scheme. Osadchy does not teach that the smart sensor is applied to pulse oximeters. Osadchy teaches that the distal end of the catheter can be used for performing electrophysical measurements. (page 11, lines 34-37 of Osadchy). Osadchy further teaches that the calibration data can be used for physiological sensors in the catheter. (page 22, lines 20-22 of Osadchy). It is well known in the art that pulse oximeters are types of physiological sensors that are placed on catheters. (column 3, lines 21-25 of Rosenheimer). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the pulse oximeter sensor of Rosenheimer on the catheter of Osadchy since Osadchy teaches physiological sensors can be used and Rosenheimer teaches one such sensor. Osadchy teaches that the calibration data of the physiological sensor is stored in the catheter. (page 22, lines 20-23 of Osadchy). It is well known in the art of pulse oximetry that memory units on the probe are used to store calibration data since it is desirable to know several parameters of a particular sensor, such as wavelength error, LED intensity, and sensor type. (column 2, lines 13-24 of Kinast). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the calibration data on the probe as disclosed by Kinast since Osadchy teaches that calibration data of the physiological sensor can be stored on the catheter and it is desirable to know several parameters of the particular sensor, such as wavelength error, LED intensity, and sensor type. In regard to claims 9-1 2 and 15, the combination teaches the use of a housing (Fig. 1 of Osadchy); the use of sensor inputs, processing circuits, and processing circuits (Fig. 5 and page 12, lines 10-20 of Osadchy; column 1, lines 20-31 of Osadchy; and Fig. 2 of Kinast); and the use of sensor reader memories (page 6, lines 7-31 of Osadchy).

Office Action, pages 5 and 6.

Applicants respectfully traverse this rejection. Each of the rejected independent claims 1, 9, and 15 recite that the sensor memory includes a "digital signature." Although the Examiner asserted that the Osadchy reference discloses a memory that "contains a digital signature in the form of a RSA encryption scheme," Applicants respectfully submit that the Examiner's assertion is in error. While it is true that the Osadchy reference discloses that calibration code may be encrypted using an RSA encryption scheme, which uses a public key and a private key, the Osadchy reference does not disclose that the calibration code is provided in the form of a digital signature or that a digital signature is otherwise provided on the memory. Indeed the Osadchy reference does not once mention the term "digital signature." The reason is quite clear: there is a difference between encrypting data (whether using an RSA encryption scheme, another public/private encryption scheme, or a symmetric encryption scheme) and providing a digital signature. To demonstrate this point, Applicants have attached as Exhibit A what appears to be a comprehensive definition of the term "digital signature." After reviewing Exhibit A, the Examiner will note that while all digital signatures are encrypted, the mere encryption of data does not generate a digital signature. Indeed, both Applicants' specification and Exhibit A describe that a digital signature is formed by computing a digest or hash and encrypting the digest or hash to create a digital signature. In sharp contrast, the Osadchy reference merely discloses that the calibration code is encrypted – it does not once mention the computation of a digest or hash or the creation of a digital signature. Because none of the art of record discloses the subject matter set forth in the rejected claims, Applicants respectfully submit that the present rejection does not support a *prima facie* case of obviousness.

In paragraphs 7 and 8 of the Official Action, the Examiner similarly rejected claims 7, 13, 17, and 18 using the present combination along with additional secondary references. However, Applicants respectfully submit that the none of the additional secondary references cure the deficiencies discussed above. Therefore, Applicants respectfully submit that claims 7, 13, 17, and 18 distinguish over the cited art for the same reasons discussed above.

In view of the remarks set forth above, Applicants respectfully submit that the subject matter of claims 1-18 is patentable over the cited art. Therefore, Applicants respectfully request withdrawal of the Examiner's rejections and allowance of claims 1-18. Finally, the Examiner rejected claims 1-8 under 35 U.S.C. § 103(a) as being unpatentable over the Cordero et al. U.S. Patent 6,298,255) ("Cordero") reference. Specifically, the Examiner stated:

> Cordero teaches a sensor system which includes a biopotential signal monitor, a smart sensor and the accompanying hardware and software interface which authenticates the source and validity of the smart sensor and also verifies that the smart sensor meets various criteria for use. (Abstract of Cordero). Cordero et al. does not explicitly state that the smart sensor is applied to pulse oximeters but Cordero teaches that the invention is related to electrophysiological sensors. (column 1, lines 9-1 2 of Cordero). Cordero further teaches four related patents that disclosed coded sensors in oximeters. (column I, line 59 to column 2, line 32 of Cordero). Cordero implies that these devices would be improved by using the smart sensor configuration to store specific data concerning the sensor itself, the date of expiration, sensor serial number, calibration data, and configuration data. (column 3, lines 6-20 of Cordero). From this information, one with ordinary skill in the art would conclude that the smart sensor configuration is applicable to oximeters. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the smart sensor configuration in an oximeter since Cordero implies that oximeters would benefit from such a configuration. In regard to claims 1 and 7, digital signature algorithms such as El Gamal and RSA public key encryption algorithms can be used. (column 17, lines 35-55 of Cordero). In regards to claim 2 and 6, the source of the smart sensor 2

> is authenticated and the integrity of its data validated by using a "digital signature." Signature generation requires the use of a "hash" function (h). In the case of a public key algorithm, the digital signature is generated using a signature generation function which typically uses both the private and public keys as well as the hashed message. (column 15, line 63 to column 16, line 37 of Cordero).

Office Action, pages 8-9.

Applicants respectfully traverse this rejection. Specifically, Applicants have attached as Exhibit B a Declaration under 37 C.F.R. 1.131 which demonstrates that the present invention was conceived of and reduced to practice prior to the effective date of the Cordero reference. The attached Declaration by co-inventor Paul D. Mannheimer states that the inventors conceived of the subject matter set forth in the present claims prior to June 9, 1999, the effective date of the Cordero reference. Indeed, a review of Declaration Exhibit 1, which was produced prior to June 9, 1999, clearly demonstrates that the subject matter of representative claim 1 was reduced to a tangible written form, thus evidencing conception. Furthermore, Mr. Mannheimer states that he and other employees of Nellcor Puritan Bennett Incorporation, the present assignee, were involved in an ongoing engineering project relating to the presently disclosed and claimed subject matter from prior to June 9, 1999, through the end of 1999. Indeed, Mr. Mannheimer states that work on the project took place on a substantially daily basis during that period of time. Therefore, regarding a constructive reduction to practice, Applicants have clearly demonstrated diligence from prior to the effective date of the Cordero reference to the priority filing date of the present application, specifically September 28, 1999. Furthermore, Mr. Mannheimer states that the sensor memory was successfully programmed with data relating to the sensor and with a digital signature at least as early as August 31, 1999, as evidenced by Declaration Exhibit 2.

Thus, Applicants have demonstrated an actual reduction of practice at least as early as August 31, 1999, coupled with diligence from prior to June 9, 1999, until the actual reduction to practice.

In view of the facts set forth in the attached Declaration and the arguments presented above, Applicants respectfully submit that the presently claimed subject matter was conceived of prior to effective date of the Cordero reference, that Applicants invention was both actually and constructively reduced to practice within a few months of the filing of the Cordero application, and that diligence was exercised from prior to the filing date of the Cordero reference until both the actual and constructive reductions to practice. Therefore, Applicants respectfully request withdrawal of the Cordero reference and allowance of the presently pending claims.

Rejections Based Upon Obviousness Double Patenting

The Examiner has rejected claims 1, 4, 5, 8, and 15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, and 20 of Berson et al., U.S. Pat. No. 6,708,049 to ("Berson"). Although Applicants do not necessarily agree with the Examiner's rejection, Applicants recognize that the present application claims priority to the Berson patent so the filing of a terminal disclaimer will not alter the term of any patent issuing from the present application. Further, Applicants have no intention of dividing ownership in any event. Therefore, Applicants have attached as Exhibit C a properly executed terminal disclaimer to obviate this rejection.

General Authorization for Extensions of Time

In accordance with 37 C.F.R. § 1.136, Applicants hereby provide a general authorization to treat this and any future reply requiring an extension of time as incorporating a request therefore. Furthermore, the Commissioner is authorized to charge Deposit Account No. 06-1315; Order No. TYHC:0053-2/FLE.

Conclusion

In view of the remarks set forth above, Applicants respectfully request allowance of claims 1-20. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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